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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------|--------------------------|---------------------|------------------|
| 10/549,250 | 05/18/2006 | Carlos Garcia-Echeverria | PAT032910A-US-PCT | 2465 |
| 29490 | 7590 | 10/12/2010 | | |
| GENOMICS INSTITUTE OF THE NOVARTIS RESEARCH FOUNDATION 10675 JOHN JAY HOPKINS DRIVE, SUITE E225 SAN DIEGO, CA 92121-1127 | | | | |
| | | | EXAMINER | |
| | | | RAO, DEEPAK R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |
| | | | | |
| NOTIFICATION DATE | DELIVERY MODE | | | |
| 10/12/2010 | ELECTRONIC | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ssesnovich@gnf.org
IPLegal@gnf.org
jclarke@gnf.org

| | | |
|------------------------------|------------------------|--------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/549,250 | GARCIA-ECHEVERRIA ET AL. |
| | Examiner Deepak Rao | Art Unit 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 August 2010.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3, 10, 11, 13, 14 and 25-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3, 10, 11, 13, 14 and 25-35 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statements (PTO/SB/06)
Paper No(s)/Mail Date 20100921

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2010 has been entered.

Claims 1-3, 10-11, 13-14 and 25-35 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

Claim Rejections - 35 USC § 103

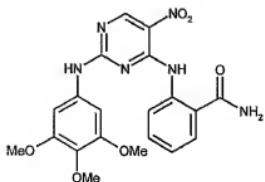
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-3, 10-11, 13-14 and 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis-Ward et al., WO 2004/074244 (effective filing date: February 20, 2003).

The reference teaches pyrimidine-2,4-diamine compounds that are structurally analogous to instantly claimed compounds. See the compounds of formula (I) in page 3, wherein Y can be $-C(O)R^8$, $-S(O)_2N(R^9)_2$, etc. wherein R^8 is $-N(R^6)_2$, etc.; up to five R^5 substituents on the phenyl ring which is at the 2-position of the pyrimidine ring attached via $-N(R^3)_2$; and the corresponding species of the examples, see for example, the compound of Example 3, Example 5, etc. The compounds are taught to be useful as pharmaceutical agents, see pages 7-8. The instant claims differ from the reference by reciting specific species or a more limited subgenus than the reference. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Alternatively, the instantly claimed compounds require a non-hydrogen substituent at the *ortho* position (or 2-position) of the ring attached to the 2-amino group of the pyrimidine (i.e., in the claims R_{10} is required to be a non-hydrogen substituent as defined in the claims). The reference discloses specific pyrimidine compounds which contain substituents at the 3-, 4- and/or

5-positions, see the compounds of the examples 3, 5, etc. (a representative structure depicted below):



The reference, however, generically teaches that the substituent R⁵ can be present at any of the ring carbons of the phenyl ring which is attached to the 2-position of the pyrimidine ring, attached via -N(R³)-. The instant claims differ from the reference compounds by requiring a non-hydrogen substituent at a position different from the reference disclosed specific compounds, i.e., at the 2-position and therefore, the instantly claimed compounds are positional isomers of the reference compounds. It would have been obvious to one having ordinary skill in the art at the time of the invention to prepare the instantly claimed compounds because they are positional isomers of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such isomeric compounds are suggestive of one another and would be expected to share similar properties and therefore, the same use as taught for the reference compounds, i.e., as pharmaceutical agents. It has been held that a compound, which is structurally isomeric with a compound of prior art is *prima facie* obvious absent unexpected results. *In re Finley*, 81 USPQ 383 (CCPA 1949); *In re Norris*, 84 USPQ 458 (CCPA 1950); *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (Fed. Cir. 1990).

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the WO'244 reference does not teach or suggest the instantly

claimed genus'. Contrary to applicant's arguments, the reference teaches a genus of formula I, see page 3, wherein Y can be selected from, among others, $-S(O)_eR^9$ wherein e is 0, 1 or 2; and R^9 can be alkyl, aryl, etc.; or Y together with the adjacent carbon atom may form a fused ring system of formula A as shown in page 4. Accordingly, the reference teaches a genus that embraces the instantly claimed genus and further discloses compounds falling within the reference genus. Thus, the reference suggests to one of ordinary skill in the art structural analogs of the reference disclosed compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such isomeric compounds are suggestive of one another and would be expected to share similar properties and therefore, the same use as taught for the reference compounds, i.e., as pharmaceutical agents.

2. Claims 1-3, 10-11, 13-14 and 25-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-42 of copending application No. 10/568,367. The reasons from the previous office action are incorporated here by reference.

Applicant's arguments that 'the rejection should be withdrawn as the reference application has a later filing date' have been fully considered. The rejection, however, is maintained until the claims in this application are otherwise found allowable. At that time the guidelines of MPEP 804 will be followed with regards to this provisional obviousness-type double patenting rejection.

Receipt is acknowledged of the Information Disclosure Statement filed on September 21, 2010 and a copy is enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Deepak Rao/
Primary Examiner
Art Unit 1624*

October 2, 2010